



## CONFERENCE REPORT ON BIOTERRORISM PREPAREDNESS ACT

Today, the House will consider the conference agreement on H.R. 3448, Public Health Security and Bioterrorism Preparedness and Response Act. The conference agreement authorizes funds for all levels of government to prepare for and respond to bioterrorist attacks and other public health emergencies. This agreement contains numerous provisions, including provisions to:

- Authorize funding to build up vaccine and drug stockpiles to combat biochemical contamination;
- Help state and local health officials prepare for bioterrorist attacks;
- Beef up public health laboratories and improve their communications;
- Expand food safety inspections;
- Better ensure the safety of drinking water supplies; and
- Create an assistant secretary of emergency preparedness within the Department of Health and Human Services to coordinate responses to any bioterror attack.

Following is an overview of the conference agreement's provisions.

### ***Bioterrorism Preparedness Provisions***

The conference agreement authorizes funding to help national, state and local governments prepare for bioterrorism incidents and other public health emergencies. It includes the following:

- **Emergency Medical Stockpiles.** Authorizes \$1.15 billion in FY 2002 and such sums as may be necessary in the succeeding years for the Health and Human Services Department to expand the current stockpiles of vaccines, medicines and other supplies. That figure includes \$509 million in FY 2002 to purchase additional smallpox vaccines. The agreement requires HHS to maintain a stockpile of drugs, vaccines and other biological products and supplies in order to meet the emergency health requirements of the U.S. population in the event of a bioterrorist attack or other public health emergency.



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- **Centers for Disease Control.** Authorizes \$300 million to upgrade and expand Centers for Disease Control and Prevention (CDC) facilities.
- **State and Local Preparedness.** Authorizes \$1.6 billion in FY 2003, and such sums as may be necessary in FY 2004 through FY 2006, for grants to states, local governments and public and private health care facilities to improve planning and preparedness activities, enhance laboratory capacity, educate and train health care personnel, and develop new drugs, therapies, and vaccines. Of the amount authorized for FY 2003, the agreement reserves \$520 million for state grants to enhance the preparedness of hospitals (including children's hospitals), clinics, health centers and primary care facilities for bioterrorism and other public health emergencies.
- **Antimicrobial Resistance.** Authorizes \$25 million in each of fiscal years 2002 and 2003, and such sums as may be necessary in FY 2004 through 2006, to be devoted to research into anti-microbial-resistant pathogens.

In addition, the agreement requires HHS to continue the development and implementation of a plan to carry out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies. The agreement also establishes an assistant secretary for emergency preparedness to coordinate HHS efforts under the measure, and authorizes a national disaster medical system to provide for further national capacity during public health emergencies.

## ***Controls on Dangerous Biological Agents Provisions***

The conference agreement includes a number of provisions intended to increase controls on the possession and handling of dangerous biological agents and toxins. For example, it expands current regulations regarding the transfer of "select agents" (i.e., the 36 biological agents or toxins the CDC determines to pose a "severe threat to public health and safety"), to require that all persons who possess or use such agents must register with HHS and must be subject to reasonable safety and security requirements and inspections. It directs HHS to maintain a national database of all such agents, with information sufficient to facilitate their identification and traceability. It requires HHS, in consultation with the Justice Department, to establish specific security requirements for registered facilities and a personnel screening protocol to ensure that certain individuals, such as those being sought for violent criminal or terrorist activity, do not have access to such agents. Finally, it also grants the Agriculture Department similar authority to regulate these agents that have the potential to pose "a severe threat to animal or plant health, or to animal or plant products."



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### ***Food Safety Provisions***

The conference agreement authorizes \$100 million in FY 2002 and such sums as may be necessary in FY 2003 through 2006, in order to increase food inspection. It directs HHS to give the highest priority to increasing FDA inspections of food at ports of entry, with special emphasis on detecting the intentional adulteration of food.

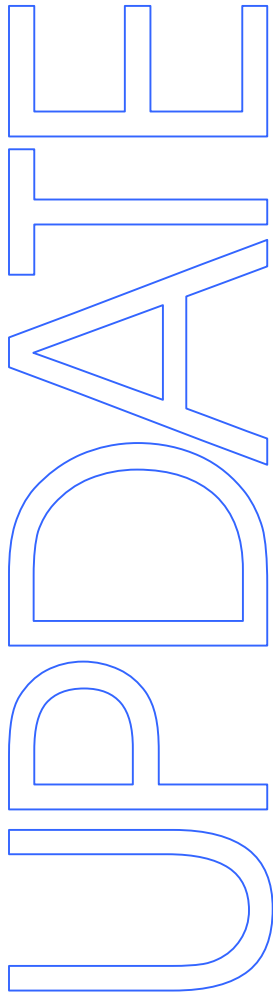
The agreement also includes the following provisions:

- **Detaining Food.** Provides the FDA with the authority to order the detention of articles of food for up to 30 days when there is credible evidence or information that the food presents a serious health threat to humans or animals.
- **Barring Certain Food Importers.** Authorizes the FDA to bar any persons convicted of a felony related to food importation, or who repeatedly imports food that they knew or should have known was adulterated or misbranded, from importing food.
- **Increased Inspections.** Authorizes the FDA to require food importers to notify the FDA of food shipments in advance of their arrival at a port of entry. If notice is not given, the food could be held at the port of entry until the FDA determines that it provides no health threat.
- **Registration.** Requires that all facilities that manufacture, process, pack or hold food for consumption in the United States must register with the FDA.
- **Prohibition on Port Shopping.** Prohibits a food importer whose shipment has been barred at one port from seeking to import it through another port.
- **Notification to States.** Requires that if the FDA has information indicating that imported food poses a serious threat to health, it must notify the states to which it believes the food has been shipped.

### ***Drinking Water Safety Provisions***

The conference agreement authorizes \$160 million in FY 2002 and such sums as may be necessary in the succeeding years to help protect the safety of water systems.

- **Vulnerability Assessments.** Requires community water systems that serve more than 3,330 individuals to conduct a vulnerability assessment. This requirement covers approximately 8,300 water



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systems. Under the measure, the 353 largest water systems – which together serve 116 million people – must complete their vulnerability assessments within one year.

- **Emergency Response Plans.** Requires community water systems serving more than 3,330 individuals to prepare an emergency response plan that incorporates the results of the vulnerability assessment – or to update their emergency response plan to incorporate those results. The EPA is also to provide guidance to systems serving fewer than 3,300 persons on how to conduct vulnerability assessments, prepare emergency response plans and address threats.
- **Preventing Intentional Contamination.** Authorizes \$15 million in FY 2002 and such sums as may be necessary in the succeeding years to help the EPA, in consultation with the CDC and other appropriate agencies to review methods to prevent, detect, and respond to the intentional introduction of chemical, biological, or radiological contaminants into community water systems and to review means to prevent supply disruption.

### ***Prescription Drug User Fee Act Reauthorization Provisions***

The conference agreement reauthorizes the FDA's prescription drug user fee program through FY 2007. These provisions authorize user fees totaling \$1.2 billion over the five-year period, FY 2003 through FY 2007. The funds derived from these fees are used by the FDA to review new drugs for safety and effectiveness and to enhance the safety review of drugs already on the market.

The agreement also authorizes additional funding for the FDA's Office of Drug Safety, the Office of Generic Drugs, and Division of Drug Marketing, Advertising and Communications.

### ***Miscellaneous Medicare Provisions***

Finally, the conference agreement also includes provisions that delay from July 1 to the second Monday in September the filing date for managed care plans to decide whether to stay in the Medicare +Choice program. This change of date would apply in 2002, 2003, and 2004.

The agreement also delays for three years the so-called "lock-in" rule that limits how often Medicare beneficiaries may change plans.